K060067

510(K) SUMMARY

JUL 14 2006

Contact Person: Elaine Duncan
Paladin Medical Inc.
PO Box 560
Stillwater MN 55082
Tel: (715) 549 6035
Fax: (715) 549 5380

Brand Name:	Maskmedic Concept Nasal Mask
Common Name:	Nasal Mask
Classification Name:	Non-continuous ventilator (21CFR 868.5905)
Product Code:	BZD
Predicate Device:	Resmed Mirage Activa (K030798)
Date Prepared:	21 December 2005; Revised July 10, 2006

Description Of The Device:
The device is a silicone elastomer nasal mask composed of a moulded, form fitting face mask, connected to standard 16 mm ventilator tubing via a standard 22 mm terminal fitting and fitted with a neoprene harness.

Indications For Use:
The Maskmedic Concept Nasal Mask is indicated for use as an accessory nasal mask with standard Continuous Positive Airway Pressure (CPAP) and bi-level positive airway treatment devices and other non continuous ventilators. The mask is suitable for use in medical facilities or for patient home use. It is intended for single patient/multi-use.

Summary of Equivalence: The Maskmedic Concept Nasal Mask is substantially equivalent to the Resmed Mirage Activa (K030798). Both the Maskmedic Concept Nasal Mask and the predicate devices are nasal masks suitable for use with currently marketed standard Continuous Positive Airway Pressure (CPAP) and bi-level positive airway treatment devices.

The technical designs and manufacture are essentially identical to the predicate devices, being composed of a form fitting nasal mask and harness, and connected to 16 mm ventilator tubing via a standard 22 mm terminal fitting. Comparative performance testing has demonstrated performance equivalent to the predicate device, and the performance of the device is not compromised by storage in extreme environmental conditions or after cleaning. A risk assessment concluded that there were no significant new safety concerns raised by the design of the Maskmedic Concept Nasal Mask.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 2006

Maskmedic Pty. Ltd.
C/O Ms. Elaine Duncan
President
Paladin Medical, Incorporated
P.O. Box 560
Stillwater, Minnesota 55082

Re: K060067
Trade/Device Name: Maskmedic Concept Nasal Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: July 10, 2006
Received: July 11, 2006

Dear Ms. Duncan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

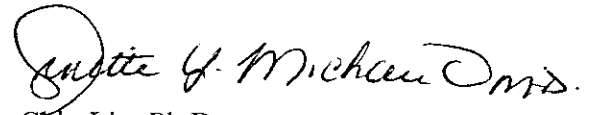
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060067:

Device Name: Maskmedic Concept Nasal Mask

Indications For Use:

The Maskmedic Concept Nasal Mask is indicated for use as an accessory nasal mask with standard Continuous Positive Airway Pressure (CPAP) and bi-level positive airway treatment devices and other non continuous ventilators. The mask is suitable for use in medical facilities or for patient home use. It is intended for single patient/multi-use

Prescription Use ✓ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

...on Sign-Off)
...n of Anesthesiology, General Hospital,
...tion Control, Dental Devices
...Number: K060067